

REMARKS

After entry of this amendment, claims 1-35 will be pending for the Examiner's review and consideration. The Applicant would first like to thank the Examiner for the allowance of the subject matter disclosed within claims 26, and 30-32. The Office Action dated October 1, 2004 has been carefully considered. Claims 1 and 22 have been amended. No new matter has been added. Claims 5, 7-16, 19, 23-25, and 27-29 have been withdrawn pending allowance of a generic claim. Reconsideration and allowance of the present application in view of the above amendments and the following remarks is respectfully requested.

In the Office Action dated October 1, 2004, the Examiner:

- objected to the amendment dated September 29, 2003 under 35 U.S.C. § 132 for introducing new matter into the disclosure. Specifically, the Examiner objected to the inclusion of Figure 8a and all the amendments to the specification to support Figure 8a;
- objected to the drawings;
- rejected claims 1-4, 6, 17, 18, 20, 21, and 33-35 under 35 U.S.C. §101 as being directed to non-statutory subject matter;
- rejected claims 1-4, 6, 17, 18, 20-22, and 33-35 under 35 U.S.C. § 102(a) as being anticipated by WO 98/34552 to Ray ("Ray"); and
- allowed claims 26, and 30-32.

35 U.S.C. § 132 Rejection

The Examiner has objected to the amendment dated September 29, 2003 under 35 U.S.C. § 132 because it introduces new matter into the disclosure. Specifically, the Examiner objected to the inclusion of Figure 8a and all the amendments to the specification which accompanied the inclusion of Figure 8a.

It is respectfully requested that the amendment dated September 29, 2003 did not enclose any new matter. Specifically, Figure 8a and the accompanying amendments to the specification were added in response to the Examiner's objection that the drawings must show every feature of the invention specified in the claims.

Furthermore, it is respectfully submitted that the amendment simply made explicit what was already implicit in the application - that one of ordinary skill in the art would have recognized that the general concepts disclosed within the specification relating to, *inter alia*,

removable blades, varying blade insertion lengths, and varying blade angles would be equally applicable to all embodiments. Specifically, one of ordinary skill in the art would recognize that these general concepts could just as readily apply to the single blade embodiment as to the dual blade embodiment.

Moreover, support for the amendment dated September 29, 2003 can be found throughout the specification, for example, in discussing Figures 14-16, the specification states that “blades 244 of distractor 200 preferably are fixedly secured to jaws 214, such as by formation of blades 244 and jaws 214 as a unitary piece.” This explicitly implies that the blades 244 do not have to be fixedly secured to the jaws 214. Thus, as one of ordinary skill in the art would recognize, the blades 244 could be removeably associated with the jaws 214 as previously disclosed within the specification. Furthermore, the specification consistently emphasizes that concepts disclosed in regards to the single blade embodiments are equally applicable to the dual blade embodiment depicted in Figures 14-16. For example, the specification states that vertebral engagers, transverse engagement walls, and/or the distractor mechanism previously disclosed are equally applicable to the dual blade embodiment. In addition, the specification states that “the foregoing description and drawings represent the preferred embodiments of the present invention [and that] it will be understood that various additions and/or substitutions may be made therein without departing from the spirit and scope of the present invention ... One skilled in the art will appreciate that the invention may be used with many modifications of structure, forms, arrangement, ... and components ... without departing from the principles of the present invention. The presently disclosed embodiments are therefore to be considered in all respects as illustrative and not restrictive ...” It is respectfully submitted that one of ordinary skill in the art would appreciate/recognize that removable blades, varying blade insertion lengths, and varying blade angles as described within the specification would be equally applicable to all embodiments disclosed within the specification.

However, in an effort to expedite prosecution of the present application, the Applicants have respectfully amended the specification to remove the changes made in the Amendment dated September 29, 2003 without prejudice to be pursued in a continuation, divisional, and/or continuation-in-part if the Applicants so desire. It should be noted that under no circumstances should the cancellation of material be perceived as an admission, as it is respectfully submitted that one skilled in the art would recognize from the disclosure of the

application that removable blades, varying blade insertion lengths, and varying blade angles as described within the specification would be equally applicable to the dual blade embodiment.

Replacement drawing sheet 5 is attached hereto as Appendix A.

Drawing Rejection

The Examiner objected to the drawings. Specifically, the Examiner objected to Figure 14 for mislabeling the jaws as “212” as opposed to “214” as provided for in the specification. The Examiner also objected to Figure 14 for mislabeling the blades as “214” as opposed to “244” as provided for in the specification. Furthermore, the Examiner objected to Figure 16 for mislabeling the spaced apart distance between the blades as “T” as opposed to “D” as provided for in the specification. Finally, the Examiner objected to Figures 14-16 for failing to indicate the thickness “T” as provided for in the specification.

In compliance with 37 CFR 1.121(d) a replacement drawing sheet 9 (copy attached as Appendix B) is provided showing appropriate changes in red for the Examiner’s approval. Upon Examiner’s approval a revised Formal Drawing in compliance with 37 CFR 1.84 will be provided.

35 U.S.C. § 101 Rejection

Independent claim 1 was rejected under 35 U.S.C. § 101 for being directed to non-statutory subject matter. Specifically, independent claim 1 was rejected for positively reciting anatomical elements. In response thereto, independent claim 1, in accordance with the Examiner’s recommendation, has been amended to recite “wherein said first and second sets of blades are configured and adapted to contact anatomical elements to be distracted ...” Withdrawal of this rejection and allowance of independent claim 1 is respectfully requested.

35 U.S.C. § 102 Rejection

Independent claims 1 and 22 were rejected under 35 U.S.C. § 102(a) as being anticipated by Ray. Independent claim 1 has been amended to recite, *inter alia*, a distractor comprising a first set of blades; said first set of blades comprising at least a first blade and a second blade, said first and second blades being separated by a dimension sufficient to permit

the complete insertion of an entire bone fusion implant therebetween; and a second set of blades; said second set of blades comprising at least a first blade and a second blade, said first and second blades being separated by a dimension sufficient to permit the complete insertion of the implant therebetween; wherein said first and second sets of blades are configured and adapted to contact anatomical elements to be distracted and permit complete insertion of the entire bone fusion implant between said anatomical elements. It is respectfully submitted that Ray does not disclose, teach, or suggest a first set of blades comprising a first blade and a second blade and a second set of blades comprising a first blade and a second blade wherein the first and second blades are separated by a distance sufficient to permit the complete insertion of an entire bone fusion implant therebetween.

Rather, Ray discloses an insertion-distractor mechanism having, *inter alia*, tool tips 24 which are insertable into a fusion device comprising halves 10 and a core 27. In operation, a hole is pre-drilled into adjacent vertebrae sized and configured to receive the halves 10. Thereafter, the tool tips 24 are inserted into the halves 10 until a limit stop 22 abuts against a proximal slotted rib 11 formed in the halves 10. Therein, the tool tips 24 are used to spread apart the halves 10 and thus the adjacent vertebra which are engaged thereto so that the porous core 27 can be inserted therebetween. More specifically, Ray discloses a three piece implant including a pair of halves 10 and a porous central core 27, and an insertion-distractor mechanism including tool tips 24 wherein the tool tips 24 include a set of paired tips 32 sized and configured to engage notches 15 formed on both sides of each halve 10 so that the paired tips 32 can be inserted into the implant so that the tool tips 24 along with the implant are inserted into a hole pre-drilled in adjacent vertebra. Actuation of the insertion-distractor mechanism spreads apart the paired tips 32, which spreads apart the implant halves 10, which causes the adjacent vertebra to spread apart so that the porous core 27 can be inserted between the fusion halves 10. Thus, Ray discloses a distractor wherein the tips engage each halve of the three-piece implant so that movement of the tips causes the implant halves to separate so that the porous core can be inserted therebetween. There is absolutely no disclosure, teaching, or suggestion in Ray of first and second blades separated by a distance sufficient enough to permit the insertion of an entire implant therebetween. Thus, it is respectfully submitted that Ray does not disclose, teach, or suggest all of the elements of independent claim 1. Therefore, independent claim 1 is allowable over the cited

prior art. Withdrawal of this rejection and allowance of independent claim 1 is respectfully requested.

Claims 2, 3, 4, 6, 17-21, and 33-35 all ultimately depend from independent claim 1, and thus, it is respectfully submitted that these claims are equally allowable. Withdrawal of these rejections and allowance of claims 2, 3, 4, 6, 17-21, and 33-35 is therefore respectfully requested.

Independent claim 22 requires, *inter alia*, a method of distracting adjacent vertebrae comprising the steps of providing a distractor comprising first and second handles, first and second jaws respectively coupled to said first and second handles, a first set of spaced apart blades extending from said first jaw, a second set of spaced apart blades extending from said second jaw, and a distractor mechanism coupled between said handles and said jaws; positioning said first set of spaced apart blades in contact against spaced apart ends of a first vertebral endplate; positioning said second set of spaced apart blades in contact against spaced apart ends of a second vertebral endplate adjacent and facing said first vertebral endplate; actuating said distractor mechanism to distract said first and second vertebral endplates; and inserting an implant between said first and second sets of blades and said first and second vertebral endplates. It is respectfully submitted that Ray does not disclose, teach, or suggest positioning a first and second set of spaced apart blades in contact against spaced apart ends of first and second vertebral endplates, respectively.

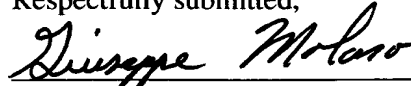
Rather, as previously described, Ray discloses an insertion-distractor mechanism including tool tips 24 wherein the tool tips 24 include a set of paired tips 32 sized and configured to engage notches 15 formed on both sides of an implant so that the paired tips 32 can be inserted into the implant. Thereafter, the tool tips 24 along with the implant are inserted into a hole pre-drilled in adjacent vertebra. Actuation of the insertion-distractor mechanism spreads apart the paired tips 32, which spreads apart the implant halves 10, which causes the adjacent vertebra to spread apart so that a porous core 27 can be inserted between the fusion halves 10. Thus, there is absolutely no disclosure, teaching, or suggestion in Ray of positioning a first set of spaced apart blades and a second set of spaced apart blades in contact against spaced apart ends of first and second vertebral endplates, respectively.

Thus, it is respectfully submitted that Ray does not disclose, teach, or suggest all of the elements of independent claim 22. Therefore, independent claim 22 is allowable over the cited prior art. Withdrawal of this rejection and allowance of independent claim 22 is respectfully requested.

In light of the above amendments and remarks, it is respectfully submitted that claims 1-35 are now in condition for allowance, and the Examiner is respectfully requested to reconsider this application with a view towards allowance. The Examiner is invited to call the undersigned attorney at 212-326-7883, if a telephone call could help resolve any remaining issues.

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Respectfully submitted,



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